

REMARKS

The Office Action of September 25, 2001 presents the examination of claims 1-9 and 11-16. Claim 9 is allowed, while claim 4 is objected to. Claims 1-3, 5-8 and 11-16 remain rejected. Claim 2 is amended into independent form. Claims 17 and 18 are added. Support for claims 17 and 18 is found on page 18 and in Example 15, pages 76-80, of the substitute specification, respectively. A marked-up version of the claims showing the changes made is attached hereto. No new matter is inserted into the application.

**Rejection under 35 U.S.C. § 102**

The Examiner maintains the rejection of claims 1-3, 5-8, and 11-15 under 35 U.S.C. § 102(b) for allegedly being anticipated by Evans '429 (USP 5,298,429). Applicants respectfully traverse. Reconsideration of the claims and withdrawal of the instant rejection are respectfully requested.

Applicants respectfully submit that Evans '429 fails to describe or suggest a cell securely maintaining a DNA comprising in a molecule a selective marker and a reporter gene. In contrast, the claims of the present application clearly recite that the reporter gene and the selective marker gene comprise a

DNA in a molecule. Evans '429 fails to describe a cell securely maintaining a DNA comprising the selective marker and reporter gene in a molecule. Evans '429, in describing the test cell, fails to describe the conditions in which the selective marker and the reporter gene are present therein. It follows that Evans '429 fails to describe that in the test cell, the selective marker is in a molecule with the reporter gene.

Further, Evans '429 fails to provide any specific description of the reporter gene or selective marker to determine the condition of the reporter gene relative to the selective marker. As explained in the Reply filed on July 3, 2001, Evans '429 in II.F.(d) CELL TRANSFECTION AND CAT ASSAY, teaches that pMTVCAT is introduced into a CV-1 cell with the calcium phosphate coprecipitation described in Wigler et al (Cell, 16:777-785(1979)). Evans '429 further teaches without citation in column 42 that pMTVCAT is a gift from S. Gould. However, the disclosure of Evans '429 fails to describe or suggest that the selective marker and the reporter gene are in a molecule, before the introduction of pMTVCAT into the CV-1 cell. Due to the lack of description, it intuitively follows that Evans '429 fails to describe the pMTVCAT after introduction into the CV-1 cell. One of ordinary skill in the art would not be

able to determine the condition of the reporter gene relative to the selective marker in the test cell. Thus, one of ordinary skill in the art would not be convinced that the selective marker and the reporter gene are in a molecule, as recited in the instant claims.

For the above reason, Applicants respectfully submit that Evans '429 fails to anticipate the present invention. Withdrawal of the instant rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103**

The Examiner maintains the rejection claim 16 under 35 U.S.C. § 102(b) for allegedly being obvious over Evans '429 (USP 5,298,429). Applicants respectfully traverse. Reconsideration of the claim and withdrawal of the instant rejection are respectfully requested.

The Examiner asserts that one of ordinary skill in the art would allegedly be motivated to use "different selection marker genes for each plasmid when carrying out co-transfection protocols." Applicants respectfully disagree with the Examiner's assertions. However, whether or not this statement is hypothetically true, the Examiner has failed to meet the requirements of obviousness under 35 U.S.C. § 103 so that the

rejection is technically deficient. To be "obvious" under the meaning of 35 U.S.C. § 103, the prior art must teach or suggest each and every claimed element of the present invention. In this case, Evans '429 fails to teach or suggest a cell securely maintaining a DNA comprising in a molecule, a selective marker and reporter gene. Thus, Evans '429 fails to obviate the present invention.

As noted above, Evans '429 fails to describe or suggest a cell securely maintaining a DNA comprising a selective marker and a reporter gene in a molecule. Evans '429 provides no impetus to modify the test cell thereof so that the selective marker and the reporter gene are present in a molecule. As such, the disclosure of Evans '429 is not sufficient to provide a basis for rejecting claim 16 under 35 U.S.C. § 103.

For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections and objections, and to issue a notice of allowance indicating the patentability of the present claims. Early and favorable action of the merits of the present application is thereby respectfully requested.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the

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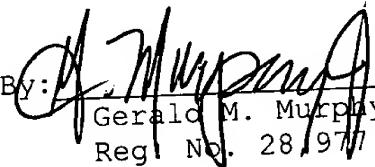
Examiner is respectfully requested to contact Kristi L. Rupert,  
Ph.D. (Reg. No. 45,702) at (703) 205-8000.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and  
1.136(a), the Applicants hereby petition for an extension of one  
(1) month to January 25, 2002 in which to file a reply to the  
Office Action. The required fee of \$110.00 is enclosed herewith.

If necessary, the Commissioner is hereby authorized in  
this, concurrent, and further replies, to charge payment or  
credit any overpayment to Deposit Account No. 02-2448 for any  
additional fees required under 37 C.F.R. § 1.16 or under 37  
C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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GMM/KLR/bsh

2185-0424P

Attachment: Version with Markings to Show Changes Made

MARKED UP VERSION SHOWING CHANGES MADE

OPPE IN THE CLAIMS  
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JAN 25 2002 The foll  
PATENT & TRADEMARK OFFICE Claim 2.  
said] An ar

The following claim is amended:

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Claim 2. (Amended) [The cell according to claim 1, wherein  
said] An animal cell expressing a gene coding a ligand-  
responsive transcription control factor and securely maintaining  
a DNA comprising in a molecule, the following genes (a) and (b):

- (a) a reporter gene connected downstream from a transcription control region, in which said transcription control region substantially consists of a recognition sequence of said ligand-responsive transcription control factor and a minimum promoter substantially [consists] consisting of a TATA box which can function in said cell and

(b) a selective marker gene which can function in said cell;

provided that the following gene (c):

- (c) a reporter gene connected downstream from a promoter which transcription activity is unchanged by having a ligand-responsive transcription control factor contacted with a ligand of said ligand-responsive transcription control factor, said reporter gene (c)

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coding a protein which can be differentiated from the  
protein coded by said gene (a)  
is not present in said cell.

Claims 17 and 18 are newly added.